JUN 2 1 2012

510(K) SUMMARY K 121028

ETVIEW TRACHEOSCOPIC VENTILATION TUBE SYSTEM (TVT™)

510(k) Number K_____

Applicant's Name: ETView Ltd.
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Trade Name: ***ETView Tracheoscopic Ventilation Tube System (TVT™)***

Device Type: Tracheal tube
Preparation Date: April 01, 2012

Classification and Classification Name:

Name: Tracheal tube
Product Code: BTR
Regulation No: 21 868.5730
Class: II
Panel: Anesthesiology

Indications for Use Statement:

The ETView ***Tracheoscopic Ventilation Tube (TVT^{TM})*** is intended for intubation procedures. The ETView ***Tracheoscopic Ventilation Tube (TVT^{TM})*** is indicated for use as a temporary

artificial airway in adults requiring mechanical ventilation. It is intended for oral and nasal intubations.

The ***TVT™*** System is indicated for viewing during non-difficult and difficult intubation procedures, for verifying endotracheal tube and endobronchial blocker placement and repositioning, for viewing during suctioning and for general inspection of the airway.

Device Description:

The ETView ***Tracheoscopic Ventilation Tube (TVT™)*** is a single use, cuffed device that functions as a standard endotracheal tube (ETT) and additionally has an embedded video imaging device embedded in a dedicated lumen. The system provides a video image of the patient's trachea, which is displayed on the monitor, for as long as the TVT™ is inside the patient's trachea.

Predicate Device: substantially equivalent to the following predicate devices:

Device Name	510k No	Date of Clearance
ETView Tracheoscopic Ventilation Tube (TVT™)	K082420	October 8, 2008
Coopdech Endobronchial Blocker tube	K093888	March 16, 2010

Performance Standards

ETView Tracheoscopic Ventilation Tube (TVT™) was tested and complies with the following standards:

- ISO 5361:1999 Anesthetic and respiratory equipment -- Tracheal tubes and connectors
- ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide
- ISO 14971-1:2007 Risk management for medical devices

- ISO 10993-1:2003(E), Biological evaluation of medical devices - - Part 1: Evaluation and testing

A detailed description appears in **Section 14**.

Performance Testing

Performance testing demonstrated that the ***ETView Tracheoscopic Ventilation Tube (TVT™)*** is as safe and effective as the cleared predicate device. The performance testing demonstrated that the minor addition to the indication for use is safe and effective. A detailed description appears in **Section 14.**

Technological Characteristics

Both the proposed ETView ***Tracheoscopic Ventilation Tube (TVT™)*** device and its predicate device (ETView Tracheoscopic Ventilation Tube k082420) function as a standard endotracheal tube (ETT) that additionally has an embedded video imaging device in a dedicated lumen. The system provides video image of patient's trachea that is displayed for as long as the ETT is inside the patient's trachea.

Biocompatibility:

Materials of the ETView ***Tracheoscopic Ventilation Tube (TVT™)*** system that are in contact with the human body, are identical to the predicate (K082420) and were tested and found to be biocompatible in accordance with ISO 10993-1.

Conclusion:

ETView Ltd. believes that, based on the information provided in this submission, the proposed ETView ***Tracheoscopic Ventilation Tube (TVT™)*** System is substantially equivalent to its predicate device without raising any new safety and/or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Etview Limited
C/O Mr. Yoram Levy
Regulatory Consultant
Qsite
31 Haavoda Street
Binyamina 30500 Israel

JUN 21 2012

Re: K121028
Trade/Device Name: ETView Tracheoscopic Ventilation Tube (TVT™)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: April 1, 2012
Received: April 5, 2012

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: ETView ***Tracheoscopic Ventilation Tube (TVT™)***

Indications for Use: The ETView ***Tracheoscopic Ventilation Tube (TVT™)*** is intended for intubation procedures. The ETView ***Tracheoscopic Ventilation Tube (TVT™)*** is indicated for use as a temporary artificial airway in adults requiring mechanical ventilation. It is intended for oral and nasal intubations.

The ***TVT™*** System is indicated for viewing during non-difficult and difficult intubation procedures, for verifying endotracheal tube and endobronchial blocker placement and repositioning, for viewing during suctioning and for general inspection of the airway.

Prescription Use _x____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices 510(k) Number

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121028